News

FDA seeks to modify regulation of medical devices

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Recent rapid responses

FDA seeks to modify regulation of medical devices: challenges for resource-poor settings?

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The Centre for Devices and Radiological Health (CDRH) at the US Food and Drug Administration (FDA) has recently decided to review the assessments on the 510(k) premarket process and to proactively facilitate medical device innovation (1).

Such initiatives are certainly challenging. In particular, the initiative on device innovation aims at "identifying unmet public health needs" and at facilitating the development or redesign of a device to address those needs", and it could bring potential benefits also for the patients in resource-poor settings. In fact, "unmet public health needs" are defined in the FDA website (1) as "those illnesses and injuries that are serious or have moderate adverse impact on health, but affect many individuals; or that could be cured, significantly improved or prevented by the development or redesign of a device; or for which the device is not being developed or redesigned due to barriers that the Federal Government can directly or indirectly remove or minimize". Actually, many of those diseases that "could be cured, significantly improved or prevented by the development or redesign of a device" are neglected diseases, mainly prevalent in resource-poor countries and for which in vitro diagnostics are either lacking or they are inappropriate for use in poor settings. Among them, we can mention the Chagas disease, for which a test of cure is still missing; visceral leishmaniasis, where improvement is needed for test case-management; and tuberculosis, a high-burden disease whose management in public health settings in developing countries is seriously challenged by the lack of a point-of-care test appropriate for resource-poor contexts (2-3).

The lack of research and development is not the only barrier to quality diagnosis and cure in resource-limited settings. The presence, on those markets, of in vitro diagnostics whose quality has not been verified according to stringent criteria may also represent a problem (4). This may be due to poor regulatory oversight (5) and to insufficient national and international guidance on their design and quality assurance. When regulatory oversight is insufficient, the FDA approval is often taken as proof of quality for diagnostic products (specifically, the 510(k) premarket process, where the majority of parasitic test fall in, is often referred to) (4). In this perspective, the planned review of the assessments on the 510(k) premarket process can be beneficial for developing countries, especially if accompanied by transparent information -sharing on quality requirements for manufacturing and verifying medical and diagnostic devices. The same recommendation would apply to the European "CE mark", which is also often taken as proof of quality for diagnostics in resource-poor countries.

Developing innovative in vitro diagnostics, and assuring the quality of those put on the market, are equally crucial measures to improve the quality of disease management in developing countries, so contributing to reduce the existing North-South gap in access to health.

(1) http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm212...

(2) Diagnostics for the developing world. Mabey D, Peeling RW, Ustianowski A, Perkins MD. Nat Rev Microbiol. 2004 Mar;2(3):231-40. Review.

(3) Requirements for high impact diagnostics in the developing world. Urdea M, Penny LA, Olmsted SS, Giovanni MY, Kaspar P, Shepherd A, Wilson P, Dahl CA, Buchsbaum S, Moeller G, Hay Burgess DC. Nature. 2006 Nov 23;444 Suppl 1:73-9.

(4) Substandard and counterfeit medical devices and in vitro diagnostics in resource limited settings: a review. Mori M, Ravinetto R., Jacobs J. (submitted).

(5) African Medicines Regulatory Harmonization Initiative (AMRHI): a WHO concept paper. WHO Drug Information Vol. 22, No 3, 2008. Available at WHO website

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